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Mr. Mathy Stanislaus
Mail Code: 5101T
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Washington, D.C. 20460

Dear Mr. Stanislaus

You may recognize me as the individual who conducted pioneering work for the USEPA between 1986 and 2006 developing a new protocol for assessing asbestos-related risks (Berman and Crump 2003) and companion methods for the determination of asbestos in air (Berman and Chatfield 1990, Chatfield and Berman 1990) and in soils or other bulk materials (Berman and Kolk 1997, 2000). The protocol, which was subjected to a peer-review consultation in 2003 (ERG 2003) and was favorably received (although with suggestions for improvements), was unique because it addressed the effects of fiber size and type. A slightly revised version (incorporating a sensitivity analysis) has since been published in the peer-reviewed literature (Berman and Crump 2008a,b) and, for convenience, copies are attached. Those publications were also followed by a peer-reviewed study (Berman 2010a) incorporating new data from a South Carolina textile plant that, among other things, suggests that the biggest unresolved discrepancy among asbestos epidemiology studies can in fact be reconciled. The study also generated an informative exchange of comments with Drs. John Dement and Leslie Stayner (Berman 2010b). Copies of these are also attached.

I also thought you would be interested in my most recent publication on this topic (Berman 2011- attached), which shows that differences in risks predicted, respectively, using the Berman and Crump or current EPA protocol (IRIS current, EPA 2008) is due primarily to: (1) arbitrary selection of the lowest of available mesothelioma potency factors (K_M's) to generate the EPA slope factor (rather than a mean or upper bound) and (2) reliance on an untested model to support the assumption that chrysotile and amphibole asbestos are equipotent. Interestingly, when that model is fit to data available today, even that model shows a significant difference in potency between the two asbestos types. Thus, adjusting for these differences, the two protocols can be completely reconciled. Another important conclusion of the paper is that, without these adjustments, the current EPA protocol provides severe underestimates of amphibole asbestos-related risks (relative to our protocol).

Until 2006, I had been working with EPA to collect samples from multiple sites studied by epidemiologists to develop data suitable for reconstructing exposures relevant to those studies so that Dr. Kenny Crump and I could then complete an improved meta analysis to better define

(perhaps definitively) both the character of asbestos structures that contribute to cancer risk and the potency factor(s) with which they could be combined to best predict cancer risk. That study was discontinued, however, when it became apparent that we would not be able to collect some of the most critical samples. Since that time, with the help of the National Stone, Sand, and Gravel Association (NSSGA), I have continued to pursue collection of bulk samples relevant to the epidemiology studies of interest. I have already collected substantial numbers of samples (of both ore and every grade product) from the chrysotile mines in Quebec (which contain small amounts of amphibole that contribute to risk in those mines); the vermiculite mine in Libby, MT; and the Johns Manville asbestos products manufacturing site in New Orleans. We are also finalizing plans to collect samples from the crocidolite mines in Wittenoom, Australia and are working with mine operators to finalize plans to collect samples from the Homestake (hard-rock gold) Mine in SD, the taconite mines in MN, and the Vanderbilt talc mine in upstate NY; all of these have been the subject of epidemiology studies evaluating exposures to various forms of amphibole.

I also know that EPA tried unsuccessfully to continue this work in 2008 with another researcher (USEPA 2008) and I provided constructive comments on their proposal (Berman 2008), which anticipated several of the comments ultimately offered by the SAB review committee (Kane 2008). Importantly, while my approach and that explored by EPA in 2008 share some common components, they also differ radically in critical respects, which apparently doomed the 2008 approach. Among the most important of differences is generation of new data being an integral component of my approach (coupled with more sophisticated statistical procedures) where the EPA 2008 approach relied solely on use of sophisticated statistical procedures. Thus, the SAB committee was right in pointing out that sophisticated statistics is not a substitute for missing data (although statistics can improve the chance of reaching the right answer when data are of limited quality).

I am also working to validate use of the elutriator (Berman and Kolk 1997, 2000, Berman 2000) for reconstructing dusts in the laboratory with characteristics that mimic those generated in the field (given similar source material); this is an important component of the larger study. In fact, the attached study (Berman 2010a,b), although not definitive (elutriator performance was not the primary focus of that study), certainly suggests that the elutriator performs as expected; the study indicates that elutriator-generated dusts are reasonably similar in character to dusts observed on archived air filters from the South Carolina textile plant evaluated by Dement and coworkers (Dement et al. 2008, Stayner et al. 2008). I also pointed out in that study that correlation between the character of dusts generated in the field and by the elutriator, respectively, is expected based on previously published geological studies addressing the factors that determine the characteristics of generated dusts; in general, they are driven primarily by the nature of the material from which the dust derives rather than the nature of the mechanical processes by which the dust is being generated.

I am now also conducting a more formal study to directly determine the degree with which the characteristics of elutriator-generated dusts mimic those of dusts encountered in the field (when generated from the same starting material) and I will be happy to share results with EPA as soon as the study is completed. I anticipate that findings from this new study will further reinforce the results of the 2010 study.

Assuming results of the current elutriator study turn out as anticipated, I am curious whether EPA might be interested in helping to support completion of (an expanded version of) the amphibole study that was discontinued in 2006. Even a simple expression of interest would be helpful.

I would like to thank you for your time and consideration and I look forward to hearing back.

Sincerely,

D. Wayne Berman, Ph.D.
President

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